

**CIBA VISION Nelfilcon A Daily Wear Soft Contact Lenses
510(k) Summary of Safety and Substantial Equivalence**

510(k) Summary

K 083216

1. Submitter Information:

Company: CIBA VISION® Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

APR 14 2009

Contact Person: Martina Heim, PhD, RAC
Senior Regulatory Specialist, Global Regulatory Affairs
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Date Prepared: 27 October 2008

2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: Focus® DAILIES®, Focus® DAILIES® Toric,
Focus® DAILIES® Progressives
- Classification Name: Daily Wear Soft Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]


3. Predicate Device:

Predicate devices are:

- 1) Focus® DAILIES®, Focus® DAILIES® Toric, and Focus® DAILIES® Progressives (nelfilcon A) One-Day Contact Lenses, as cleared under K050065,
- 2) FreshLook®, FreshLook® Toric, and FreshLook® Progressives (nelfilcon A) One-Day Color Contact Lens, as cleared under K050213.

4. Description of Device:

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). For VISITINT® lenses, the color additive phthalocyanine blue (also known as copper phthalocyanine) is added to the lens material to create a light blue edge to edge color to make them easier to see when handling. The lenses may be printed with inks containing one or more of the following color additives: phthalocyanine blue, phthalocyanine green.

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Focus® DAILIES®, Focus® DAILIES® Toric, Focus® DAILIES® Progressives One-Day contact lenses include spherical, toric, and multifocal lens designs in the following parameter ranges:

- Power Range: -20.00D to +20.00D
- Center Thickness: 0.010 mm for -3.00D spherical (varies with power)

Lenses have the following properties:

- Refractive index: 1.38
- Light transmittance: approximately 96 %T
- Water content : 69% by weight
- Oxygen permeability 26 barrer
measured at 35°C (single point Dk-Polarographic method)


Lenses are supplied sterile in sealed blister-packs containing buffered saline. The compatibility and package integrity of the blister-pack packaging system has been demonstrated and successfully used for other CIBA VISION marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister-pack containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility). Shelf-life studies are ongoing to establish and extend the labeled expiration date.

5. Indications for Use:

Focus® DAILIES® and Focus® DAILIES® Toric (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

Focus® DAILIES® Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single-use daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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6. Substantial Equivalence:

The following matrix summarizes the characteristics of the modified device as compared to the predicate devices:

	Modified Device	K050065	K050213
	Focus DAILIES Family (nelfilcon A) One-Day Soft Contact Lens	Focus DAILIES Family (nelfilcon A) One-Day Contact Lens	FreshLook Family (nelfilcon A) One-Day Color Contact Lens
Lens Material:	nelfilcon A	nelfilcon A	nelfilcon A
Material Classification:	FDA Group 2 (> 50% H ₂ O, nonionic polymer)	FDA Group 2 (> 50% H ₂ O, nonionic polymer)	FDA Group 2 (> 50% H ₂ O, nonionic polymer)
Water Content:	69%	69%	69%
Power Range:	+20.00 to -20.00D	+20.00 to -20.00D	+20.00 to -20.00D
Visibility Tint:	With or without copper phthalocyanine	With or without copper phthalocyanine	With or without copper phthalocyanine
Manufacturing Method:	Lightstream Technology™: Full mold cast, integrated print step	Lightstream Technology™: Full mold cast	Lightstream Technology™: Full mold cast, integrated print step
Lens Designs:	Spherical, toric, multifocal	Spherical, toric, multifocal	Spherical, toric, multifocal
Sterilization:	Steam sterilization, validated autoclave	Steam sterilization, validated autoclave	Steam sterilization, validated autoclave
Packaging:	Blister pack	Blister pack	Blister pack
Package Storage saline solution	Phosphate-acetate buffered saline with up to 0.02% Poloxamer 108	Phosphate-acetate buffered saline with up to 0.02% Poloxamer 108	Phosphate-acetate buffered saline with up to 0.02% Poloxamer 108

Non-clinical Testing:

Successful stability testing supports the labeled expiration date. Additional chemical, physical, and toxicological testing results can be referenced from the predicate devices.

Clinical Testing:

The scope of the device modification did not require clinical testing to establish safety and effectiveness of the modified device.

Substantial Equivalence:

The Focus® DAILIES®, Focus® DAILIES® Toric, and Focus® DAILIES® Progressives (nelfilcon A) One-Day Contact Lenses are substantially equivalent to the predicate

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lenses and similar to other daily wear soft contact lenses in terms of water content (69% water) and ionic characteristics (FDA Group II: high water, nonionic), clinical performance, and indications for use.

Any differences which may exist between the Focus® DAILIES®, Focus® DAILIES® Toric, and Focus® DAILIES® Progressives (nelfilcon A) One-Day Contact Lenses and other Group II soft hydrophilic contact lenses do not adversely affect the safety and effectiveness of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CIBA VISION Corporation
c/o Martina Heim, Ph.D., RAC
Senior Regulatory Specialist
11460 Johns Creek Parkway
Duluth, Georgia 30097

APR 14 2009

Re: K083216

Trade/Device Name: Focus® DAILIES®, Focus® DAILIES® Toric,
Focus® DAILIES® Progressives

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) contact lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: March 24, 2009

Received: March 25, 2009

Dear Dr. Heim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

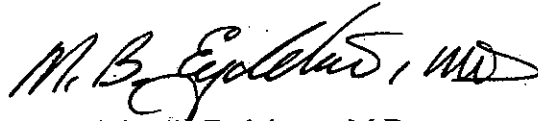
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. B. Eydelman, MD". The signature is fluid and cursive, with the "MD" at the end being more distinct.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PART II. INDICATIONS FOR USE STATEMENT

510(k) Number: K083216

Device Name: Focus® DAILIES®, Focus® DAILIES® Toric,
Focus® DAILIES® Progressives

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☒ or ☐ Over the Counter Use

Ming-Chuan Shih

(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

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